

## REMARKS

### **I. Introduction**

Claims 21, 22, 24-30 and 32-43 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

### **II. Rejection of Claims 25, 26, 30, 32-37 and 43 Under 35 U.S.C. §112**

Claims 25, 26, 30, 32-37 and 43 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It is believed that the presently pending claims satisfy the requirements of 35 U.S.C. 112, first paragraph.

For instance, the Office Action contends that, with respect to claims 25 and 36, “[t]he original specification does not provide support for ... the mask opening portion is formed from a partially flexible material, such that the mask opening portion substantially maintains its shape as the mask opening portion is inserted into and seated within a patient.” Office Action at page 2. Applicant respectfully disagrees. For example, the Specification describes the material from which the airway tube 200 is made at page 11, lines 13-15 as “polyvinyl chloride (PVC), or any other known inexpensive, durable and partially flexible material...”. Emphasis added. Thus, as an initial matter, the Specification explicitly states that polyvinyl chloride (PVC) is a partially flexible material. Furthermore, the Specification states at page 13, lines 29-32, that “the entire mask portion 100 could be integrally molded in one piece from a durable biocompatible material such as urethane or polyvinyl chloride (PVC).” Thus, since the Specification explicitly describes that the mask portion may be polyvinyl chloride (PVC), and since the Specification also explicitly describes that polyvinyl chloride (PVC) is a partially flexible material, then it is evident that the Specification provides support under 35 U.S.C. § 112 for the recitation that “the mask opening portion is formed from a partially flexible material.”

Furthermore, various figures, e.g., Figure 1, illustrate the mask opening portion having a shape prior to the mask opening portion being inserted into and seated within a patient. In addition, other figures, e.g., Figures 7 and 8, illustrate the mask opening portion having substantially the same shape after the mask opening portion has been inserted into and seated within a patient. Thus, since the Specification explicitly discloses that the mask opening portion has the same shape both before and after the mask opening portion is inserted into and seated within a patient, then it is evident that the Specification provides support under 35 U.S.C. § 112 for the recitation that “that the mask opening portion substantially maintains its shape as the mask opening portion is inserted into and seated within a patient.” It is therefore respectfully submitted that claims 25 and 36 fully comply

with the requirements of 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is therefore respectfully requested.

In addition, the Office Action contends that, with respect to claim 26, “[t]he original specification does not provide support for ... wherein the tubular member is sufficiently rigid to prevent crushing or kinking.” Office Action at page 2. Applicant respectfully disagrees. However, for the purposes of expediting the prosecution of this application, Applicant has amended claim 26 to recite that “the elongate tubular member is ... sufficiently rigid to permit the elongate tubular member to be positioned in a patient and to provide an effective airway which is not readily blocked or obstructed during use.” Support for this amendment can be found, for example, in the Specification at page 11, lines 7-16, which states that “the airway tube 200 is made of a material which is ... sufficiently stiff to permit the airway tube 200 and the mask portion 100 to be accurately positioned manually in the patient P.” The Specification also states at page 4, lines 1-6, that “[t]he present invention is also designed ... to provide an effective airway which is not readily blocked or obstructed during use.” It is therefore respectfully submitted that claim 26 fully complies with the requirements of 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is therefore respectfully requested.

In addition, the Office Action contends that, with respect to claims 30 and 43, “[t]he original specification does not provide support for ... wherein the grate is flexible enough such that the flexible grate material defining apertures between the grate is displaceable.” Office Action at page 2. Applicant respectfully disagrees. However, for the purposes of expediting the prosecution of this application, Applicant has amended claims 30 and 43 to recite that “the flexible grate material defining apertures between the bars of the grate.” Support for this amendment can be found, for example, in the Specification at page 14, lines 22-23, which states that “the mask opening 111 is formed by a plurality of apertures 142.” In addition, the Specification states at page 14, lines 28-29, that “[t]he apertures 142 are separated from one another by a series of bars forming a grate.” It is therefore respectfully submitted that claims 30 and 43, and claims 32-35 and 37 which depend from claim 30, fully comply with the requirements of 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is therefore respectfully requested.

### **III. Allowable Subject Matter**

Claims 21, 22, 24, 27-29 and 38-42 are allowed.

### **IV. Request For Interference**

Applicants respectfully request that, since it is believed that all of the pending claims of the present application are now in condition for allowance, an interference be

declared between claims 21, 22, 24-30 and 32-43 of the present application and claims 1 to 39 of U.S. Patent No. 6,386,199 ("the '199 patent"), for the reasons set forth in Applicant's previously filed "Amendment and Request for Interference" filed in the U.S. Patent and Trademark Office on May 13, 2003 and additionally for the reasons set forth in Applicant's Amendment and Third Request for Interference submitted October 25, 2004, and additionally for the reasons set forth below.

As set forth above, Applicant has amended claim 26 to recite that "the elongate tubular member is ... sufficiently rigid to permit the elongate tubular member to be positioned in a patient and to provide an effective airway which is not readily blocked or obstructed during use." The Specification states at page 11, lines 7-16, that "the airway tube 200 is made of a material which is ... sufficiently stiff to permit the airway tube 200 and the mask portion 100 to be accurately positioned manually in the patient P." The Specification also states at page 4, lines 1-6, that "[t]he present invention is also designed ... to provide an effective airway which is not readily blocked or obstructed during use."

Claim 7 of the '199 patent recites "the elongate tubular member is ... reinforced to prevent crushing or kinking." The '199 patent states that "[the] structure ... is rigid enough to assure proper placement and to prevent inadvertent kinking of the airway." Column 7, lines 36-38. In addition, the '199 patent states that "[t]he tubular member further is radially robust to not kink during insertion or manipulation." Column 12, lines 14-16. Therefore, the rigidity of the respective tubular members of the present application and the '199 patent are described as performing the same function, e.g., maintaining an unobstructed passage through the airway tube during and after the insertion of the airway tube into a patient.

Applicant therefore respectfully maintains that, by virtue of the fact that the rigidity of the tubular members of the present application and the '199 patent perform the same function and in the context of the claims are directed to the same patentable invention, an interference should be declared between claim 26 of the present application — which include the limitation that "the elongate tubular member is ... sufficiently rigid to permit the elongate tubular member to be positioned in a patient and to provide an effective airway which is not readily blocked or obstructed during use" — and claim 7 of the '199 patent — which include the limitation that "the elongate tubular member is ... reinforced to prevent crushing or kinking."

As set forth above, Applicant has amended claims 30 and 43 to recite "the grate being made of a flexible material that is rigid enough to slide the epiglottis into abutment with the wall of the mask opening portion as the mask opening portion is inserted into the hypopharynx, the flexible grate material defining apertures between the bars of the grate." The Specification states at page 14, lines 22-23, that "the mask opening 111 is formed by a plurality of apertures 142." In addition, the Specification states at page 14, lines 28-29, that "[t]he apertures 142 are separated from one another by a series of bars forming a

grate.” The Specification states at page 17, lines 27-33 that “[t]he bars and grates 143 act to restrain any anatomical portion ... from entering into and blocking or partially blocking, the mask opening 111’, thereby preventing obstruction of the delivery or removal of gases from the respiratory system of the patient P.” Still further, the Specification states at page 18, lines 22-25, that “the apertures 142 between the bars 143 increase the likelihood of establishing a ventilation path even when substantial mucousa is present.” The Specification further states that “the bars 143 may preferably form an angled surface 143a which will assist in the insertion of any tube into the larynx via the airway tube 200.”

Claim 18 of the '199 patent recites that “the grate being made of a flexible material that is rigid enough to slide the epiglottis into abutment with the anterior wall of the wedge-shaped housing as the wedge-shaped housing is inserted into the hypopharynx and flexible enough to enable an endotracheal tube to be axially driven between a gap defined by the grate by displacing the flexible grate material defining the gap.” Claim 37 of the '199 patent recites that “the grate is made of a flexible material that is rigid enough to slide the epiglottis into abutment with an anterior wall of the elongate tubular member as the wedge-shaped housing is inserted into the hypopharynx and flexible enough to enable an endotracheal tube to be axially driven between a gap defined by the grate by displacing the flexible grate material defining the gap.” The '199 patent states that “FIG. 7A further includes a plurality of bars 452 forming a grate over the leading opening 454 [wherein] the bars are rigid enough to support the epiglottis.” Column 10, lines 43 to 50. In addition, the '199 patent states that “a grate may cover the opening to keep the epiglottis and other tissue out of the opening.” Column 5, lines 29 to 30. Furthermore, the '199 patent states that “[t]he grated PLA 510 is also intended to allow blind intubation of a patient with an endotracheal tube 580.” Column 13, lines 61-62. Specifically, the '199 patent states that “the bars are ... flexible enough to allow an endotracheal tube to be inserted therebetween.” Column 10, lines 50-51. Therefore, the respective bars of the gratings, and the apertures/gaps situated between the bars of the grating, of the present application and the '199 patent are described as performing the same function, e.g., preventing any anatomical portion from entering into and blocking or partially blocking the mask opening while permitting the passage of a tube therethrough.

Applicant therefore respectfully maintains that, by virtue of the fact that the bars of the gratings, and the apertures/gaps situated between the bars of the grating, of the present application and the '199 patent perform the same function and in the context of the claims are directed to the same patentable invention, an interference should be declared between claims 30 and 43 of the present application — which include the limitation of “the grate being made of a flexible material that is rigid enough to slide the epiglottis into abutment with the wall of the mask opening portion as the mask opening portion is inserted into the hypopharynx, the flexible grate material defining apertures between the bars of the grate” — and claims 18 and 37 of the '199 patent — which include the limitations of “the

grate being made of a flexible material that is rigid enough to slide the epiglottis into abutment with the anterior wall of the wedge-shaped housing as the wedge-shaped housing is inserted into the hypopharynx and flexible enough to enable an endotracheal tube to be axially driven between a gap defined by the grate by displacing the flexible grate material defining the gap” and “the grate is made of a flexible material that is rigid enough to slide the epiglottis into abutment with an anterior wall of the elongate tubular member as the wedge-shaped housing is inserted into the hypopharynx and flexible enough to enable an endotracheal tube to be axially driven between a gap defined by the grate by displacing the flexible grate material defining the gap”, respectively.

**V. Conclusion**

Applicants respectfully submit that all of the pending claims of the present application are now in condition for allowance. Prompt reconsideration and allowance of the present application, and the declaration of the above-referenced interference proceeding, are therefore earnestly solicited.

**VI. Fees**

The Commissioner is authorized to charge any necessary fees or credit any overpayments under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

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